

REMARKS/ARGUMENTS

OATH/DECLARATION

A new oath or declaration in compliance with 37 CFR 1.67(a) is submitted herewith.

DRAWINGS

Figures 1 to 9 have been replaced with higher quality versions of the same. Further, reference numerals have been added to the drawings to refer to various elements therein. The description has been amended to insert corresponding reference numerals where appropriate for consistency with the drawings as amended. No new matter has been added by way of these amendments.

In response to the Examiner's comments, applicant respectfully refers to for example Figure 3, where representative bone anchors 1 linked with a representative support filament 2 (which comprises twisted surgical thread in the illustrated embodiment) are clearly shown. For illustrative purposes, support filament 2 has been illustrated by hand in Figure 4 to improve the illustration's contrast. In later figures, support filament 2 is no longer visible as it is coated with matrix layer 3. Figures 5 and 6 illustrate the implant following formation of a matrix layer 3 (which may or may not contain cells) surrounding the support filament. In light of the above, Applicants respectfully submit that the "bone anchors" and "support filament" are clearly shown in the drawings and respectfully request that the objection be withdrawn.

SPECIFICATION

Paragraph [0054] has been amended for clarity as requested.

Paragraphs [0054], [0058], [0060], [0062], [0063], [0065], [0072], [0073], [0078], [0084], [0090], [0097], [0100], [0106] and [0109] have been amended to introduce reference numerals consistent with the amendments to the drawings noted above. No new matter has been added by way of these amendments.

CLAIMS

The application now contains 48 claims. Claims 12, 18 and 19 have been amended to correct grammar for clarity. Claims 25-44 have been withdrawn from examination as noted by the Examiner. New claims 45 to 48 have been added, which find support, for example, in paragraphs [0058] (claim 45) and [0057] (claims 46-48) of the description. No new matter has been added by way of these amendments.

CONCERNING 35 USC § 103

Claims 1-7 and 9-16:

Claims 1-7 and 9-16 of record stand rejected pursuant to 35 USC § 103 as being allegedly unpatentable over United States Patent No. 5,613,982 (Goldstein) in view of United States Patent No. 5,067,962 (Campbell). In response, applicants respectfully submit the following.

The instant application relates to an engineered implant, which as claimed comprises a pair of bone anchors joined at their proximal ends by at least one support filament, the support filament being coated by at least one matrix layer of thickness capable of allowing colonization by a cell. The preparation of the implant entails the preparation of an anchor - support filament - anchor structure. The filament is coated by a suitable matrix layer, i.e. capable of allowing the colonization of cells. The matrix may optionally be colonized by a cell. Further, subsequent matrix layers may optionally be applied.

It is due to the elements noted above, i.e. the bone anchors, support filament and matrix layer and their inter-association which allows the preparation of such an engineered implant as described in the instant application. The bone anchors serve to define the end portions of the implant and may ultimately provide points for attachment when the implant is implanted into the recipient. The support filament is used to initially join the two anchors and to act as a foundation onto which the cell-supporting matrix layer is applied. The instant

support filament further has the added advantage of providing additional strength to the implant, rendering it more robust to facilitate its handling and preparation *ex vivo*, its surgical implantation, and to provide added strength to the implant *in vivo*, particularly during the period immediately following implantation, during which the added strength aids recovery at the site of implantation as ingrowth and integration is still at a relatively early stage. The matrix layer coats the support filament, and provides a suitable structure for cell colonization. Taken together, these three components of the implant as claimed allow the preparation of an engineered implant which may be prepared completely *ex vivo*, since a base structure may be prepared comprising the bone anchors joined by a support filament, which serves to join the anchors and also to act as a base onto which the cell-supporting matrix layer is applied. The support filament in particular plays a key role in this case, as it serves to bring the other components together, and it is therefore due in large part to the use of the support filament that the instant engineered implant structure can be so prepared. As a result of this structure, the implant as claimed in the instant application has several advantages, such as:

1. It does not require a base structure from a donor animal. Thus it is not limited by the limited availability of donor tissue, which is a significant disadvantage of transplantation technology.
2. It is not limited to xenogeneic donor tissue. Such tissue presents a significant problem of implant rejection which is well known in the art.
3. The design and constituting elements of the engineered implant of the instant application can be well controlled. Thus the implant can be engineered to have an optimal structure and characteristics (dimensions, cell type and source, incorporation of any agents/compounds) for a particular application, which results in an increased likelihood of successful implantation and integration into the recipient with decreased rejection.

In contrast, neither Goldstein nor Campbell teach or suggest a comparable “support filament” as recited in the instant claims. This is due to the fact that Goldstein and Campbell relate to natural xenograft implants rather than an engineered implant such as that of the instant application (which may be prepared *ex vivo*). As Goldstein and Campbell rely on obtaining an essentially complete implant structure from an animal donor, i.e., the base or overall structure of the implant was created in the donor *in vivo*, they do not require and as such do not teach nor suggest a central structural component comparable to the “support filament” as presently claimed, which allows the preparation of the instant engineered implant *ex vivo*.

Applicants respectfully refer to MPEP 2142, where it is noted: “To establish a *prima facie* case of obviousness...the prior art reference (or references when combined) must teach or suggest all the claim limitations.” (emphasis added). Further to the above, Applicants respectfully submit that neither Goldstein nor Campbell mentions or suggests a “support filament” as presently claimed. Thus applicants respectfully submit that the requirements to establish a *prima facie* case of obviousness have not been met.

Further, taken together, Goldstein and Campbell relate to implant structures which originate from a natural donor, and as such are in a completely different and unrelated area of implant technology, one based on transplantation of natural donor-derived tissue into a recipient, in contrast to the engineered implant of the instant application. As such, applicants respectfully submit that Goldstein and Campbell would not suggest to one of skill in the art an engineered implant as claimed in the instant application.

In view of the foregoing, applicant respectfully submits that claims 1-7 and 9-16 are inventive over Goldstein in view of Campbell and respectfully requests that the rejection be withdrawn.

Claims 8 and 17-24:

Claims 8 and 17-24 of record stand rejected pursuant to 35 USC § 103 as being allegedly unpatentable over Goldstein as modified by Campbell further in view of United States Patent No. 6,287,340 (Altman). In response, applicants respectfully submit the following.

Altman relates to the preparation of an anterior cruciate ligament (ACL) via the growth of pluripotent stem cells in a matrix, an example of which is a gel of collagen type I. The cells are cultured within the matrix to encourage their growth and regeneration while subjecting the matrix to mechanical forces. It is evident that the key focus of Altman is the application of such mechanical force.

It appears that the Examiner has thus referred to Altman to discuss the aspect of a collagen gel matrix, as a gel layer is recited in claims 8 and 17-24 of the instant application.

Similar to the comments above in reference to MPEP 2142, Applicants first wish to note that Altman also does not mention nor suggest a "support filament" as presently claimed. Thus applicant respectfully submits that the requirements to establish a *prima facie* case of obviousness have not been met.

Applicants further respectfully note that Goldstein and Campbell are in a different field of technology from Altman, which is based on the preparation of an ACL *ex vivo*, and does not utilize an *in vivo* generated structure. Therefore, one of skill in the art would not have been motivated to combine the teachings of Goldstein and Campbell with Altman.

In view of the foregoing, applicant respectfully submits that claims 8 and 17-24 are inventive over Goldstein as modified by Campbell further in view of Altman and respectfully requests that the rejection be withdrawn.

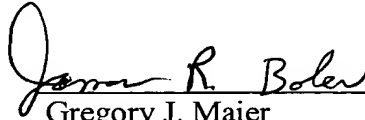
It is believed this responds to all of the Examiner's concerns, however if the Examiner has any further questions, he is invited to contact S. Serge Shahinian (Reg. No. 52,533) at

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514-954-1500. Further, if the Examiner does not consider that the application is in a form for allowance, an interview with the Examiner is respectfully requested.

Respectfully submitted,

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